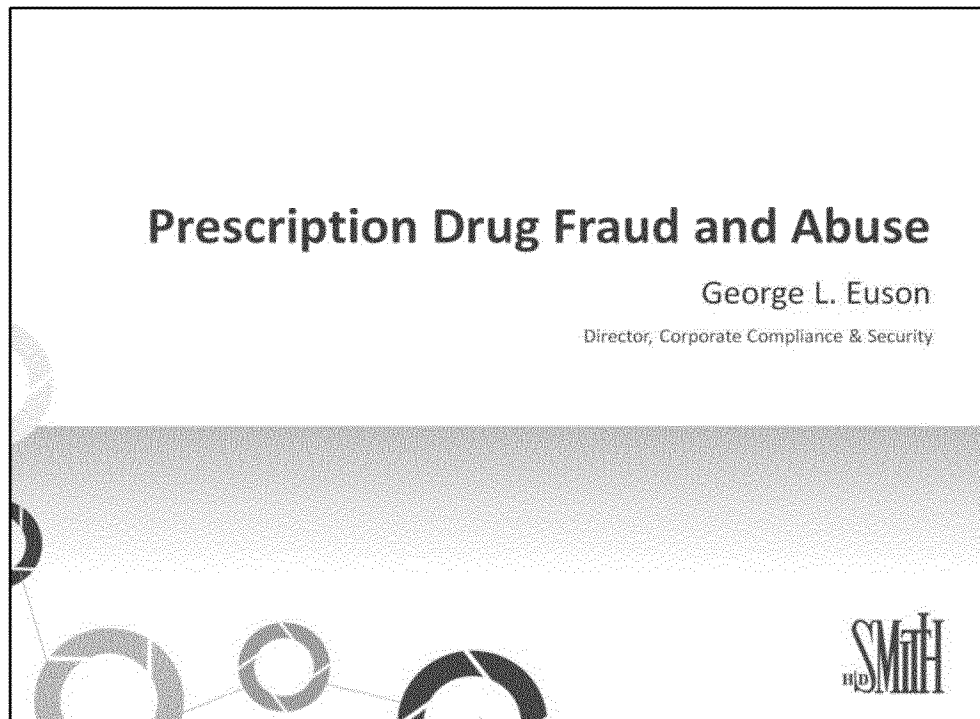


EXHIBIT 35



Business ethics....

*In the most basic terms, a definition for
business ethics boils*

*down to knowing the difference
between right and wrong and
choosing to do what is right.*

MEDICARE

- **Part D** = PRESCRIPTION DRUG PLANS

MEDICARE - not just 65 and older....

- LIS – low income subsidy
- Disabled – at a young age

Overview of Part D

- Part D: The Prescription Drug Program began on January 1, 2006
 - The government sets baseline coverage standards
 - The Plan Sponsors are private companies that set premiums, cost-sharing amounts, and coverage limits using guidelines established by the government
 - Medicare pays a set amount of money for each member on the plan
- CMS approves these plans for inclusion in the program

Who Commits the Fraud?

- Plan Sponsors and Pharmacy Benefits Managers (PBM)
- Agents/Brokers
- Pharmacies
- Prescribers/Physicians
- Opportunists and Beneficiaries

Pharmacies

- There are three kinds of pharmacies: retail, mail order, and long term care
 - Prescription drug shorting
 - Dispensing expired or adulterated prescription drugs
 - Prescription forging or altering
 - Signature Logs
 - Prior Authorization Forms
 - Prescriptions
 - Inappropriate billing practices
 - Billing for brand names when generics are dispensed
 - Billing for covered drugs when non-covered drugs are dispensed
 - Billing for non-existent prescriptions
 - Charging retail vs. negotiated price

Prescribers/Physicians

- Bill for services that are not medically necessary
- Bill for services not rendered
- Provision of false information
- Theft of prescriber's DEA number or prescription pad
- Prescription drug switching
- Script mills

Other Fraud Subjects

- Elderly beneficiaries
 - 65+
- Young beneficiaries
 - Under the age of 65
 - Disabled/ESRD
- Relatives/friends of beneficiaries
 - Pick up prescription drugs at pharmacies
 - Steal prescription drugs from medicine cabinets
- Identity theft/fraud:
 - Beneficiary representing themselves as Physician/Clinic Staff
 - Beneficiary representing themselves as another beneficiary
 - Beneficiary allowing someone else to use their benefits

Other Fraud Subjects (continued)

- Doctor shopping and pharmacy shopping
 - Multiple prescribers
 - Multiple pharmacies
 - Overlapping days supply
- Prescription forging or altering
 - E-prescription and tamper proof pads are being utilized to deter this activity
- Resale of drugs on black market
 - Multiple scripts for narcotics or other drugs sold on the street/black market

[D]

Medicare Fraud Issues

- Medicare and Medicaid pay out some \$750 billion dollars each year to more than a 1.5 million doctors, hospitals and medical suppliers. By many estimates, about \$65 billion dollars a year is lost to fraud.
- Criminals use real patient IDs to bill for wheelchairs that were never delivered or exams never performed.
- Dishonest doctors – a small percentage of physicians, to be sure – charge for care they never deliver or perform unnecessary operations. In one scam, criminals bill Medicare and a private insurer for the same patient.

[D]

Potential Solutions

- The federal health law and other legislation directed the federal government to start using sophisticated anti-fraud computer systems.
- Doctors and others who want to bill Medicare are going to be assessed based on their risk to commit fraud.
- "Pay and chase" has given way to a prevention of fraud model
- Over the next decade, Congress will direct some \$340 million dollars in additional funding for government anti-fraud efforts.
- The number of defendants facing fraud charges jumped sharply last year.

[D]

Federal Exclusion?

- Doctors, Dentists, Nurses, Pharmacists, Pharmacy Tech's (licensed healthcare professional).
 - 1st offense – 5 years to life,
 - 2nd offense - 10 years to life,
 - 3rd offense – permanent.
 - Based on healthcare fraud conviction (felony or misdemeanor).
 - Diversion - *Including admission of guilt*.
 - Cannot work for any entity that accepts any government health care program funding (medicare/medicaid).
- <http://exclusions.oig.hhs.gov/search.aspx>

[D]

Scope of Prescription Drug Abuse Problem

- 2010 Hydrocodone #1 drug prescribed in USA
- Prescription drug abuse is #2 to marijuana abuse in USA
- *# 1 cause of accidental death in the U. S.*

[D]

RX Abuse #1 cause of accidental death in US

- A government health agency says the United States is in the grip of an **epidemic of prescription drug overdoses**. The Centers for Disease Control and Prevention reports that **more people die from such overdoses than from all illegal drugs combined**. And **accidental prescription drug deaths** in the United States each year **outnumber highway traffic fatalities**.
- In many states drug overdose deaths passed auto accidents as #1 cause of accidental deaths
- About 82 Kentuckians a month die from prescription drug overdoses — that's higher than the number of people killed in highway crashes.

[D]

- More than 36,000 people died of drug overdoses in 2008
- Of those drug overdoses, prescription drugs were involved in over 20,000 cases.
- Sales of prescription painkillers since 1999 have more than tripled, and their involvement in overdose deaths has spiked as well, from 4,000 cases in 1999 to 15,000 in 2008. That's more than heroin and cocaine combined.

[D]

\$ Costs \$

How much is coming out of our pockets?

- One study puts the overall economic cost of painkiller abuse at more than \$70 billion a year.
- Pill addicts who shop around for doctors to score prescriptions cost insurers \$10,000 to \$15,000 apiece.
- The toll in lost productivity: \$42 billion.
- The criminal justice bill: \$8.2 billion.

[D]

The Tenets of Lawful Prescribing

- A lawful Rx for a controlled substance must be:
 - Issued for a legitimate medical purpose.
 - Issued by an individual practitioner acting in the usual course of their professional practice.
 - Documented in the medical chart.
- A doctor/patient relationship must exist.

[D]

Pharmacist's "Corresponding Responsibility"

- The Drug Enforcement Administration ("DEA") recently published a decision that considers the scope of a pharmacist's "corresponding responsibility" under 21 C.F.R. § 1306.04(a). East Main Street Pharmacy (Affirmance of Suspension Order) (Docket No. 09-48) (75 Fed. Reg. 66149 (Oct. 27, 2010)) ("EMS").
- 21 C.F.R. § 1306.04 provides that while "the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription."
- A pharmacist is prohibited from filling a prescription for controlled substances "when he either knows of or has reason to know that the prescription was not written for a legitimate purpose." 75 Fed. Reg. at 66163. Further, when prescriptions are not issued for a legitimate medical purpose, a "pharmacist may not intentionally *close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.*"

[D]

“Red Flags”

- The DEA addressed certain “red flags” that should have given the respondent pharmacist a “*reason to know*” that the prescriptions patients presented to him were not legitimate.
- Did the Pharmacist have “reason to know [they] were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.”
- In reviewing the pharmacist’s conduct the DEA stated that the pharmacist ignored several signs that the prescriptions written by the physician were not legitimate.
- These flags include the following:

[D]

“Red Flags”

- “ample evidence” showing that the respondent repeatedly dispensed “cocktailed” prescriptions for oxycodone, hydrocodone, alprazolam, and carisoprodol; finding that this combination prescription is “well known in the pharmacy profession as being used by patients abusing prescription drugs;”
- no individualization of dosing by the prescribing physician;
- filling multiple prescriptions for the strongest formulations of hydrocodone and alprazolam;
- requests for early dispensing of refills;
- refilling prescriptions of patients or doctors located hundreds of miles away from the pharmacy;
- an overwhelming proportion (95%) of prescriptions filled by the pharmacy were controlled substances prescriptions;

[D]

“Red Flags”

- the pharmacist did not reach out to or otherwise contact other pharmacists to determine why they were **not** filling a particular doctor's prescriptions;
- filling prescriptions of patients that travelled to the pharmacist in groups;
- filling a larger percentage of cash prescriptions. (“This too, was a red flag as ‘[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect.’”); and
- “verification” of a prescription as “legitimate” was not satisfied simply because the practitioner performed MRI's and blood tests on the patients.
- Presented with the above evidence, the DEA stated that ***even if the pharmacist had verified with the physician “each and every” prescription***, the evidence showed he still violated his corresponding responsibility because many of the prescriptions “patently served no legitimate medical purpose.”

Prescription Drug Monitoring Program

- 49 states have or are in the process of implementing a PMP (Missouri is only exception at this time)
- No mandatory utilization requirement for doctors / pharmacists
 - Voluntary compliance
 - Momentum building for mandatory utilization in 2012. (KY, MASS)
 - New patients / customers should be screened before prescribing / filling CS
 - Offer training to healthcare professionals in order to promote use

[D]

“Doctor Shopping”

Knowingly Misrepresenting/Withholding Information from
a Doctor

- Providing false information to a physician **in order to obtain, or in an attempt to obtain**, a controlled substance.
- Attempt may not lower degree of crime.
- Offenders identified by:
Pharmacists, physicians and **arrestees**.

[D]

WC Dr. Shopper case

- SNL Doctor Shopper.wmv

[D]

“Fraudulent Phone Rx’s”

- Assuming the identity of a doctor or other authorized person.
- Awareness of drug seekers watching/listening to phone conversations in waiting rooms.
- Phone in Rx’s from private room in office.
- DO NOT PHONE IN RX’S FOR PATIENTS WITHOUT FIRST CONFIRMING PATIENT IDENTIFICATION / ILLNESS.
- Drug seeker commonly phones in Rx, has (possibly unaware) “dupe” pickup Rx.
- Schedule II cannot be phoned in.
- Obtain call back number.
- Ask questions to confirm Dr.’s identity (office/home address/ph#).

[D]

Solutions to Fraudulent Phone Rx's

- **Obtain call back number!**
 - Caller ID.
- Be aware of caller providing too much information.
- Confirm suspicious Rx's with physician's office.
- Request photo ID.
- **Do not delete recordings** of fraudulent phone Rx's.
EVIDENCE!!!!!!!!!!!!
- **Be aware of police impersonators.**
 - Confirm identity by calling back on cell phone, office.
 - Ask for identifiers (badge #, office address etc.)

[D]


Solutions to Forgery, Theft & Alterations

- Confirm unusual Rx's with physician.
- Seize Rx. (Allowed by law?)
- Notify police **prior to filling.**
- Do not write on Rx.
- Obtain license number and vehicle description.
- Photo ID
- Write down physical description.
 - Clothing, speech, tattoos, glasses, hair style.
- Do not fill Rx's improperly written.
 - Notify prescribing physician / Rx Squad.
- **Seize notes as evidence (notebooks with practice signatures, DEA#'s, names DOB's)**

Theft of Identity charge

HDS_MDL_00249059

Altered MG


Physician N
Phone

Norton Hospital, 200 E. Chestnut St.
Kosair Children's Hospital, 231 E. Chestnut St.
Norton Children's Hospital, One Audubon Plaza Dr.
Norton Southwest Hospital, 9820 Third Street Rd.
Norton Suburban Hospital, 4001 Dutchmans Ln.

Name

Address

Date 5-30-05


(TS.O)
Vicodin 5mg
#8 @ 3ht
Sig: Q6h prn pain
not relieved by acet
not relieved by acet

☒ 1-24
☐ 25-49
☐ 50-74
☐ 75-100
☐ 101-150
☐ 151 and over

Refill ☒ 1 2 3 4 5


DEAR

Ky Lic



Prescription is void if more than (1) prescription is written per blank

~~~~~

**NORTON**  
COMMUNITY  
MEDICAL ASSOCIATES

3 AUDUBON PLAZA DRIVE, LOWER LEVEL 2,  
(502) 636-8005 • FAX (502)

Name

Address

Date

Case #

06-0506

3/26/19

5705 Southland Blvd

3/26/19

Hyrodan cough supp  
+ tso 8th prn  
8 oz  
4oz per  
bottle

1-24

25-49

50-74

75-100

101-150

151 and over

Refill NB 1 2 3 4 5

mail form

Prescription is void if more than (1) prescription is written per blank



~~~~~

UNIVERSITY OF MICHIGAN
330 S. Jackson Street, LANSING, MICHIGAN 48226
Physician Name: [REDACTED] License: [REDACTED]
Business Address: [REDACTED] DEA #: [REDACTED]

Name: [REDACTED]
Address: [REDACTED] Date: 3/6/07

10/10/00
i tab 80 of 64 per [REDACTED]
#80

Refill: ☒ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

S. M. M. D. D. I.

Prescription is void if more than one (1) prescription is written per blank.
and ORIGINAL DOCUMENT HAS A REASONABLE NATIONAL FAX NUMBER

Quantity changed from 30 to 80

ST. MARY & ELIZABETH HOSPITAL - Emergency Dept.
1000 Blount Avenue • Louisville, Kentucky 40215 • Phone (502) 361-6361

Dr. D. Bahrman, M.D. DEAN AB276944	Dr. G. Harrington, M.D. DEAN AD3048519
Dr. R. Carls, M.D. DEAN BC3181890	Dr. J. McKee, M.D. DEAN BA32943000
Dr. R. Clark, M.D. DEAN AC2762715	Dr. T. Mendenhall, M.D. DEAN BA11257989
Dr. W. Crecelius, M.D. DEAN BC3279981	Dr. S. Morris-Jones, M.D. DEAN BU0111984
Dr. T. Forrest, M.D. DEAN AF2834770	

Name Meyers 3

Address V. 75 3 6 c 7
(11) on 11 to 7 4-6 1/2 per year
Leg # (16) six rec

Refill NR 1 2 3 4 5

Prescription is void if more than (1) prescription is written per blank

MG changed from 5 to 7.5

~~~~~

Case #07-0452

11/30/06 08/02/78 28Y 9722108007

Phenergan C Codeine suspension  
Tsp po q 4h prn cough  
8 ounces

Refill 1 2 3 4 5

Prescription is void if more than (1) prescription is written per blank

aptist East E.R.  
(502) 897-0141  
DEAN J. EAST  
DEAN J. EAST  
DEAN J. EAST

807-8184  
Fax Hosp

ER states  
Qty was  
changed. Please  
Report immediately  
Date 11/30

☒ 1-24  
☐ 25-49  
☐ 50-74  
☐ 75-100  
☐ 101-150  
☐ 151 and over

Ounces changed from 4 to 8.

[D]

# Altered Quantity & Quantity box

Unit Health Care  
Physician Name \_\_\_\_\_ Phone # \_\_\_\_\_ License # \_\_\_\_\_  
Business Address \_\_\_\_\_ DEA # \_\_\_\_\_

Name \_\_\_\_\_  
Address \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

LOUISVILLE  
40219

1-24  
25-49  
50-74  
75-100  
☒ 101-150  
151 and over

Full/Partial 1 2 3 4 5 Void after \_\_\_\_\_

Do not deliver \_\_\_\_\_ M.D.

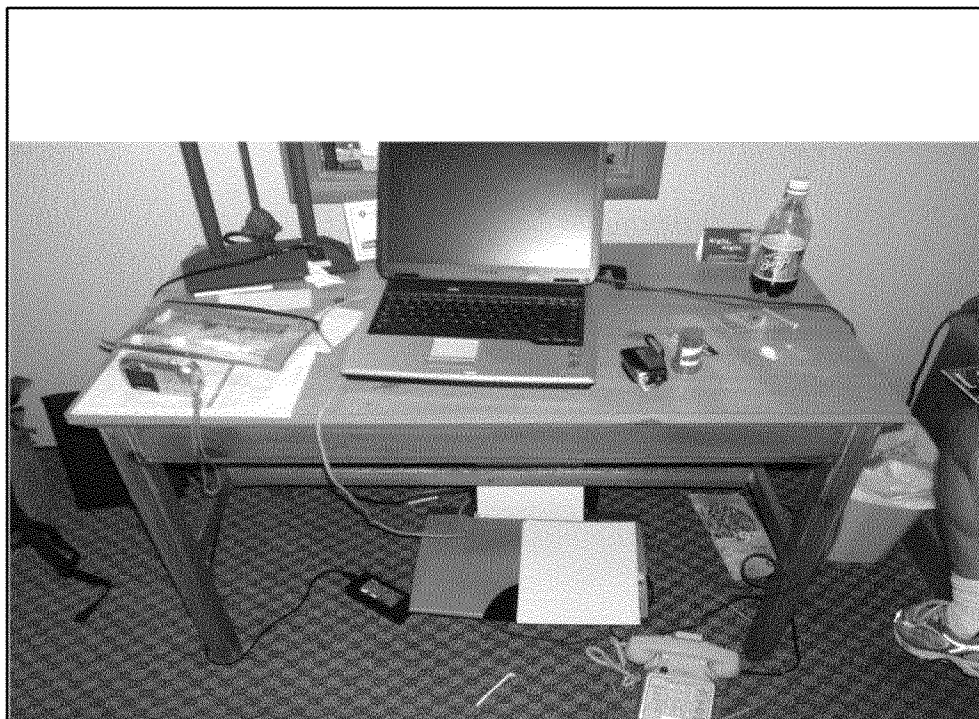
Prescription is void if more than one (1) prescription is written for blank.

[D]



[D]





[D]

## Methadone

- Schedule II.
- ***Almost one-third of prescription painkiller overdose deaths involve methadone.***
  - *Methadone accounts for only 2 % of painkiller prescriptions in the United States*
- Old drug – proven reliable, doctors are comfortable with prescribing.
- Long half life.
- Cheap.
- Opiate addiction.
- Pain management.
- 40 mg wafer only distributed at treatment centers

[D]

## Hydrocodone

- Schedule III narcotic (Can be phoned to pharmacy)
- Typically combined with acetaminophen.
  - Hepatic (liver) disorder.
- Drug seekers typically want highest mg of Hydrocodone and least amount of acetaminophen.
  - 10/325 popular

[D]



## Oxycontin® (Purdue Pharma)

- Twelve hour sustained release **Oxycodone**.
- 10, 20, 40, 80 mg. (160 mg. no longer marketed)
- Opiate (*Hillbilly heroin*).
- Moderate to severe (chronic) pain.
  - Cancer patients.
  - Chronic back pain.
- New formula released in August 2010
  - Studies show less abuse

[D]

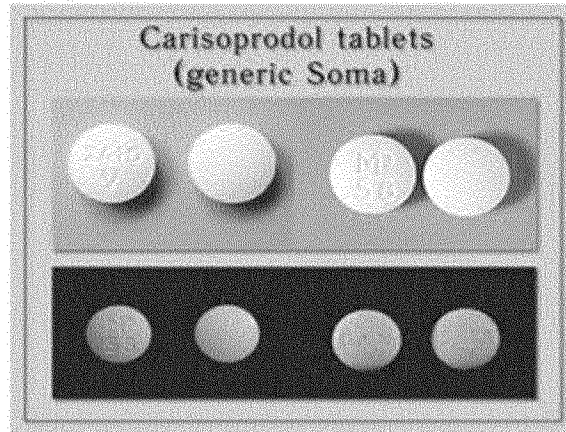
## Alprazolam (Generic)

- Brand name: Xanax®
- Schedule IV. Benzodiazepine. Anti-Anxiety.
  - Can be prescribed by phone.
  - Frequently phoned in unlawfully.
- Frequently prescribed along with a pain medication.

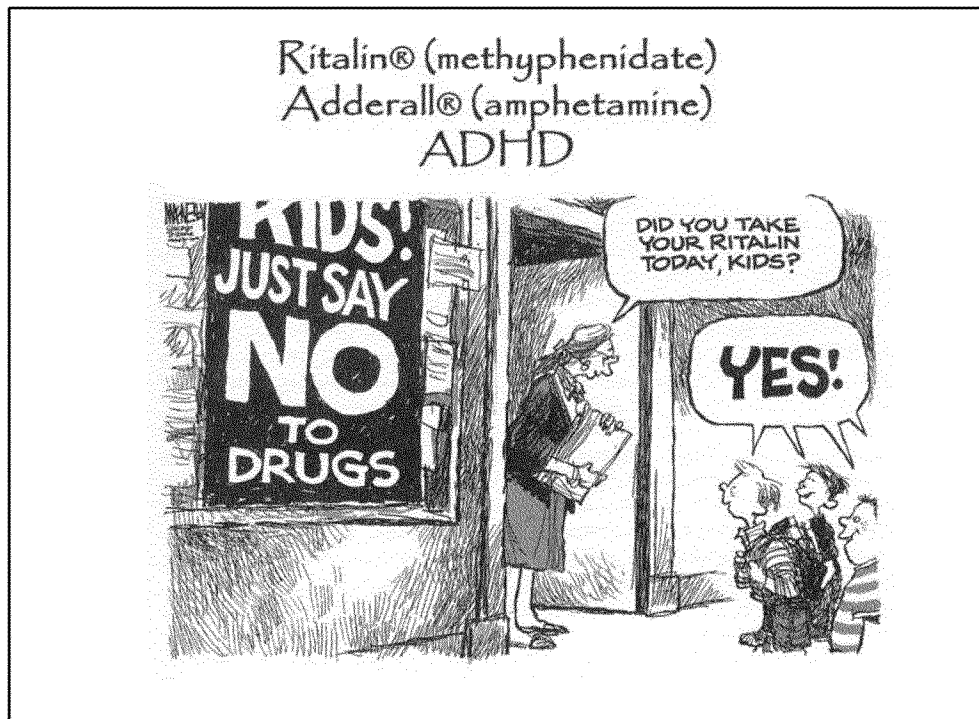
[D]

## Carisoprodol (Soma®)

- December 2011 Federally controlled substance – Schedule IV
- Muscle relaxant
- Narcotic potentiator
- Flexeril?



[D]



[D]

## Promethazine VC w/Codeine

- Schedule V.
- Opiate effects.
- Snow cone syrup bottles.
- Lean
- Candy baby bottles, soda cans.
- Illicit dealers soliciting addicts to have Rx filled.
- \$300.00 for 8oz bottle in Louisville.

[D]

## Oxymorphone

- Schedule II narcotic (semi synthetic opioid)
- Stronger analgesic than oxycodone or morphine.
- Available in both immediate release (IR) and extended release (ER).
- Approx. 10 x more potent analgesic as compared to morphine.

[D]

### **Fentanyl (Duragesic patch)**

- Transdermal patch (body heat activated and absorbed thru skin)
- Schedule II narcotic
- Approx. 100 times more potent analgesic as compared to morphine
- Highly abused in institutional setting
- 100 micrograms of fentanyl approximately equivalent to 10 mg of morphine

[D]

## DEA Concerns

- *2011 - Renewed focus on pharmacies, manufacturers and distributors*
- Wholesalers *required* to conduct due diligence on customers.
- *Excessive* amounts of schedule II drugs (oxycodone) sold.
- Integrity of domestic pharmaceutical supply.
- DEA also focusing on Manufacturers
  - Mallinckrodt
  - Watson

[D]



## Federal Updates

- Cardinal Health - Lakeland, FL
  - 2 year suspension of DEA Registration
- CVS – Sanford, FL
  - 2 stores still have their DEA registrations **REVOKED**
- Walgreens distribution center – Jupiter, FL
  - DEA suspended on September 14, 2012
    - The DEA says Walgreens failed to maintain proper controls to ensure it didn't dispense drugs to addicts and drug dealers
    - Since 2009, Walgreens Jupiter has been the single largest distributor of oxycodone in Florida
    - Six Walgreens retail stores being investigated in Florida
- Past DEA suspensions of wholesalers by DEA were a result of internet sales
  - Cardinal suspension this year was a result of lack of due diligence or their lack of action regarding the due diligence they conducted.
- DEA focus is on rogue "pill mills" and the pharmacies that service them.
- Congressional investigation in to drug shortages continue.
  - Focus on distributors price gouging
  - Focus on pharmacies purchasing these types of drugs for resale into wholesale market.

[D]

### Diversion Trends

- Since August 2010 introduction of new formulation of OxyContin, the abuse of this drug has dramatically declined.
- Coinciding with the OxyContin abuse decline was the increased abuse of generic Oxycodone 30 mg.
- We are now seeing an increased diversion of Endocet 10/325 as it appears some prescribers are moving away from the Oxycodone 30 mg due to publicity and increased scrutiny.
- Opana ER has become a popular replacement for OxyContin as a drug of choice.
  - Manufacturer recently came out with a tamper resistant pill similar to the new formulation Oxycontin.
- "Trinity" drug cocktail (Hydrocodone, Benzo & Carisoprodol) popular in TX and other areas of the southeast.
- Prometh w/codeine abuse in large urban areas.

[D]

### **Diversion Trends**

- Prescription painkillers are causing more deaths nationwide than heroin and cocaine combined.
- Prescription drug overdose deaths now outpace automobile accidents as an accidental cause of death.
- Pharmacy robberies and burglaries are on the rise.
- High street prices for prescription drugs has caused an increased use of heroin across the country.

[D]

Contact:

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[D]